

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER)	
PHARMACEUTICALS, INC., RB)	
PHARMACEUTICALS LIMITED, and)	
MONOSOL RX, LLC,)	
)	
Plaintiffs,)	REDACTED - PUBLIC VERSION
)	
v.)	C.A. No. 13-2003-RGA
)	
ALVOGEN PINE BROOK, INC.)	
)	
Defendant.)	

LETTER TO THE HONORABLE RICHARD G. ANDREWS

OF COUNSEL:

Steven H. Sklar
Gregory C. Bays
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza
180 N. Stetson Ave., Suite 4900
Chicago, IL 60601
(312) 616-5600

Karen E. Keller (No. 4489)
Jeffrey T. Castellano (No. 4837)
David M. Fry (No. 5486)
SHAW KELLER LLP
300 Delaware Avenue, Suite 1120
Wilmington, DE 19801
(302) 298-0700
kkeller@shawkeller.com
jcastellano@shawkeller.com
dfry@shawkeller.com
Attorneys for Defendants

Dated: May 7, 2014

SHAW KELLER

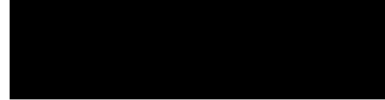
LLP

Jeffrey T. Castellano
300 Delaware Avenue, Suite 1120
Wilmington, DE 19801
(302) 298-0700
(302) 298-0703 - Direct
jcastellano@shawkeller.com

May 7, 2014

Via CM/ECF & Hand Delivery

The Honorable Richard G. Andrews
District Court for the District of Delaware
844 North King Street
Wilmington, DE 19801



Re: *Reckitt Benckiser Pharms. Inc. v. Alvogen Pine Brook, Inc.*, 13-2003-RGA

Dear Judge Andrews:

Defendant Alvogen Pine Brook, Inc. (“Alvogen”) submits this letter in response to Plaintiffs’ Motion to Dismiss pursuant to Fed. R. Civ. P. 12(b)(1) and Fed. R. Civ. P. 41(a)(2) (D.I. 51, 52). Alvogen does not oppose the relief sought in Plaintiffs’ motion, namely dismissal of Plaintiffs’ claims against Alvogen as well as Alvogen’s counterclaims against Plaintiffs. However, Alvogen submits this letter to address various inaccurate and misleading assertions in Plaintiffs’ motion.

Plaintiffs contend that Alvogen’s Paragraph IV notices were premature and untimely and, therefore, improper. Alvogen’s notices were not premature. [REDACTED]

[REDACTED] The Hatch-Waxman Act, in particular 21 U.S.C. § 355(j)(2)(B)(ii)(II), requires that notice shall be given “**at the time**” the amendment or supplement is submitted to FDA if the Paragraph IV certification is included in an amendment or supplement to the ANDA. See 21 C.F.R. § 314.95(d) (“If an abbreviated application is amended to include [a Paragraph IV certification], the applicant shall send the notice required ... **at the same time** that the amendment to the abbreviated application is submitted to FDA.”) Neither the statute nor the regulation clarify that the notice requirement can be met only after an ANDA has been accepted by FDA.



The Honorable Richard G. Andrews

Page 2

Moreover, Alvogen informed Plaintiffs of the status of its ANDA before Plaintiffs filed the original complaint (D.I. 1). As acknowledged in Plaintiffs' brief (D.I. 25 at 5 n.2), Plaintiffs initiated this action despite knowing that FDA had not yet accepted Alvogen's ANDA. As a result, Alvogen spent time and money engaged in litigation that Plaintiffs now contend is premature.

Respectfully submitted,

/s/ Jeffrey T. Castellano

Jeffrey T. Castellano (No. 4837)

CERTIFICATE OF SERVICE

I, Jeffrey T. Castellano, hereby certify that on May 7, 2014, this document was served on the persons listed below in the manner indicated:

BY E-MAIL:

MaryW. Bourke
Dana K. Severance
WOMBLE CARLYLE SANDRIDGE &
RICE, LLP
222 Delaware Avenue, Suite 1501
Wilmington, DE 19801
(302) 252-4320
mbourke@wcsr.com
dseverance@wcsr.com

James F. Hibey
Houda Morad
Timothy C. Bickman
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, NW
Washington, DC 20036
(212) 429-3000
jhibey@steptoe.com
hморad@steptoe.com
tbickman@steptoe.com

Daniel A. Ladow
Timothy P. Heaton
James M. Bollinger
TROUTMAN SANDERS LLP
405 Lexington Avenue
New York, NY 10174
(212) 704-6000
daniel.ladow@troutmansanders.com
timothy.heaton@troutmansanders.com
james.bollinger@troutmansanders.com

Troy S. Kleckley
Puja R. Patel
TROUTMAN SANDERS LLP
600 Peachtree Street, NE, Suite 5200
Atlanta, GA 30308
(404) 885-3000
troy.kleckley@troutmansanders.com
puja.patel@troutmansanders.com

/s/ Jeffrey T. Castellano

Karen E. Keller (No. 4489)
Jeffrey T. Castellano (No. 4837)
David M. Fry (No. 5486)
SHAW KELLER LLP
300 Delaware Avenue, Suite 1120
Wilmington, DE 19801
(302) 298-0700
kkeller@shawkeller.com
jcastellano@shawkeller.com
dfry@shawkeller.com
Attorneys for Defendant